

**Missouri Board of Pharmacy**

Complaint No. 2009-000814 )  
 )  
Goldsmith Pharmacy )  
777 S. New Ballas Rd. )  
St. Louis, MO 63141 )

**SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY  
AND GOLDSMITH PHARMACY**

Goldsmith Pharmacy and the State Board of Pharmacy (“Board”) enter into this settlement agreement for the purpose of resolving the question of whether Goldsmith’s license as a pharmacy will be subject to discipline.

Pursuant to the terms of § 536.060, RSMo 2007<sup>1</sup>, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Goldsmith Pharmacy acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proven upon the record by competent and substantial evidence; the right to cross-examine

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<sup>1</sup> All references are to the 2007 Missouri Revised Statutes unless otherwise stated.

any witness appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time Goldsmith Pharmacy may present evidence in mitigation of discipline; and the right to seek attorney's fees incurred in defending the Board's action against its license.

Being aware of these rights provided to it by operation of law, Goldsmith Pharmacy knowingly and voluntarily waives each and every one of these rights and freely enters into this settlement agreement and agrees to abide by the terms of this document, as they pertain to it.

Goldsmith Pharmacy acknowledges that it has received a copy of the investigative report, and other documents relied upon by the Board in determining there was cause for discipline, along with citations to law and/or regulations that the Board believes were violated. For the purpose of settling this dispute, Goldsmith Pharmacy stipulates that the factual allegations contained in this settlement agreement are true and stipulates with the Board that Goldsmith Pharmacy' license as a pharmacy, license number 5102, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo, as amended.

#### **Joint Stipulation of Facts and Conclusions of Law**

1. The State Board of Pharmacy is an agency of the State of Missouri created and established pursuant to § 338.140, RSMo, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Goldsmith Pharmacy is licensed by the Board as a pharmacy, license

number 5102. Goldsmith's license is and was at all times material herein current and active.

3. On or about February 4, 2009, a pharmacy board inspector conducted an inspection at Goldsmith Pharmacy.

Bulk non-sterile compounding without a Class D license

4. Goldsmith Pharmacy provides non-sterile compounded drugs as part of its practice.

5. Goldsmith Pharmacy makes compounded products from bulk active ingredients in batch quantity.

6. Pursuant to 2220-2.020(9)(D) Goldsmith's practice requires a Class D license:

Class D: Non-Sterile Compounding. A pharmacy that provides services as defined in section 338.010, RSMo and provides a nonsterile compounded product as defined in 20 CSR 2220-2.400(1) and meets the following criteria:

1. Any product made from any bulkactive ingredient in a batch quantity as defined in 20 CSR 2220-2.400(3).

7. Goldsmith's actions violate 338.220.1 which states in pertinent part:

338.220. 1. It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate, or maintain any pharmacy as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy. A permit shall not be required for an individual licensed pharmacist to perform nondispensing activities outside of a pharmacy, as provided by the rules of the board. A permit shall not be required for an individual licensed pharmacist to administer drugs, vaccines, and biologicals by protocol, as permitted by law, outside of a pharmacy. The following classes of pharmacy permits or licenses are hereby established:

\* \* \*

(4) Class D: Nonsterile compounding;

### Quality Control

8. Goldsmith's compounding records reflect 74 instances between October of 2007 and the end of December of 2008, where a product is recorded as being dispensed beyond the recorded expiration date for the batch the dispensing is listed for.

9. Goldsmith failed to record in its log any information regarding the batch from which the product was actually dispensed.

10. In addition, Goldsmith failed to record in its log any information regarding non-batch compounding; compounds prepared for specific prescriptions.

11. Goldsmith Pharmacy's actions violate 20 CSR 2220-2.400(7) which states:

7) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.

(A) Such methods shall include the following and shall be followed in the execution of the drug compounding process. A separate log shall be maintained which includes:

1. Methods for the compounding of drug products to insure that the finished products have the identity, strength, quality and purity they purport or are represented to possess;
2. Date of compounding;
3. Identity of the compounding pharmacist;
4. A listing of the drug products/ingredients and their amounts by weight or volume;
5. Description of the compounding process and the order of drug product/ingredient addition, if necessary for proper compounding;

6. The identity of the source, lot number and the beyond-use date of each drug product/ingredient, as well as an in-house lot number and a beyond-use date for bulk compounded products; and
7. An identifying prescription number or a readily retrievable unique identifier for which the compound was dispensed.

#### Compounding of Commercially Available Products

12. Goldsmith's records included 21 prescription records for compounded preparations for which there is a commercially available product and for which there was no documentation of the medical reason the preparation was being compounded. These products were dispensed between December 27, 2007 and December 19, 2008.

13. Goldsmith's Pharmacy's actions violate 20 CSR 2220-2.400(9) which states:

Compounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially available Federal Drug Administration (FDA) approved drug products is prohibited. There shall be sufficient documentation within the prescription record of the pharmacy of the specific medical need for a particular variation of a commercially available compound.

#### Unverified claims regarding compounded products

14. Goldsmith records revealed that on seven instances between March of 2007 and July of 2008, Goldsmith dispensed compounded products as extended release that had not been confirmed as extended release by independent testing.

15. Goldsmith's actions violate 20 CSR 2220-2.400 which states in pertinent part:

A pharmacist or pharmacy may advertise or otherwise provide information concerning the provision of compounding services; however, no pharmacist or

pharmacy shall attempt to solicit business by making specific claims about compounded products.

#### Incomplete Recall

16. Following the February inspection, Goldsmith was advised that products whose labeling was false and misleading were misbranded and needed to be recalled.

17. Goldsmith initiated a recall, but did not contact each prescriber.

18. Goldsmith's actions violate 20 CSR 2220-2.400 (8) (C), which states in pertinent part:

C) A recall must be initiated when a product is deemed to be misbranded or adulterated. The pharmacy shall notify the prescriber of the nature of the recall, the problem(s) identified and any recommended actions to ensure public health and safety.

#### Cause to discipline

19. Section 338.210.5 states in pertinent part:

5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

20. Cause exists to discipline Goldsmith Pharmacy's permit pursuant to §338.055, RSMo, which in pertinent part, states as follows:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has

surrendered his certificate of registration or authority, permit or license for any one or any combination of the following causes:

\* \* \*

(5) Incompetency, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter.

\* \* \*

(13) Violation of any professional trust or confidence;

### **Joint Agreed Disciplinary Order**

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of 621.045.3, RSMo.

1. Goldsmith Pharmacy, license number 5012 is hereby placed on PROBATION for a period of three (3) years (the “disciplinary period”). During the disciplinary period, Goldsmith Pharmacy shall abide by the following terms and conditions:

A. Goldsmith Pharmacy shall pay all required fees for licensing to the Board and shall renew its license prior to October 31 of each licensing year.

B. Goldsmith Pharmacy shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. “State” here includes the

State of Missouri and all other states and territories of the United States.

C. If requested, Goldsmith Pharmacy shall provide the Board a list of all licensed pharmacists employed by Goldsmith Pharmacy, and the individuals' current home and work addresses and telephone numbers;

D. If, after disciplinary sanctions have been imposed, Goldsmith Pharmacy fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

E. Goldsmith Pharmacy shall report to the Board, on a preprinted form supplied by the Board office, once every six months (due by each January 1 and July 1), beginning with whichever date occurs first after this Order/Agreement becomes effective, stating truthfully whether or not he has complied with all terms and conditions of its disciplinary order.

F. Goldsmith Pharmacy shall not serve as an intern training facility for interns.

G. Goldsmith Pharmacy shall select an independent Missouri-licensed pharmacist consultant for the purpose of reviewing and insuring all compliance measures are carried out in accordance with all applicable laws and regulations. Respondent shall submit documentation and credentials of its chosen consultant to the Board office for approval prior to the beginning date of probation. Said consultant shall submit a written plan to the board office outlining what procedures or changes in operation will be implemented and what time table is



proposed for completion. The consultant shall then provide ongoing reports to the Board office attesting to the pharmacy's compliance or noting deficiencies for each visit made. The visits and initial report shall be provided within thirty (30) days of the beginning of probation. Visits to the pharmacy to assess compliance will be completed at a minimum of a 6 month cycle and reports to the Board office will be provided once every 6 months throughout the disciplinary period. The consultant shall be hired at Goldsmith Pharmacy' expense.

H. Goldsmith Pharmacy shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Goldsmith Pharmacy will be notified and given sufficient time to arrange these meetings.

2. Goldsmith Pharmacy' failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Order/Agreement.

3. The parties to this settlement agreement understand that the Board of Pharmacy will maintain this settlement agreement as an open record of the Board as provided in Chapters 338, 610, and 324 RSMo.

4. The terms of this settlement agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this settlement agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

5. Goldsmith Pharmacy hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former Board members, employees, agents, and attorneys of, from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to 536.087, RSMo, or any claim arising under 42 U.S.C. 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this settlement agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this agreement in that it survives in perpetuity even in the event that any court of law deems this settlement agreement or any portion thereof void or unenforceable.

6. Goldsmith Pharmacy understands that it may, either at the time the settlement agreement is signed by all parties, or within fifteen (15) days thereafter, submit the agreement to the Administrative Hearing Commission for determination that the facts agreed to by the parties constitute grounds for disciplining Goldsmith Pharmacy's pharmacy license. If Goldsmith Pharmacy desires the Administrative Hearing Commission to review this Agreement, Goldsmith Pharmacy may submit its request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65101.

7. If Goldsmith Pharmacy requests review, this settlement agreement shall become effective on the date the Administrative Hearing Commission issues its order finding that the settlement agreement sets forth cause for disciplining Goldsmith Pharmacy's license. If Goldsmith Pharmacy does not request review by the Administrative Hearing Commission,

the settlement agreement goes into effect fifteen (15) days after the document is signed by the Executive Director of the Board.

LICENSEE

By: 

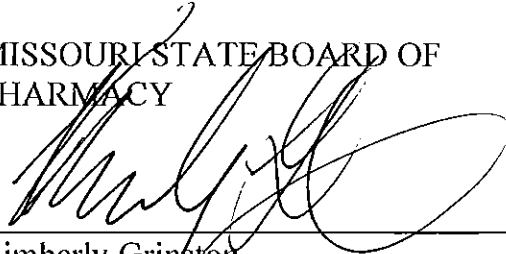
Title

OWNER

Date

5-26-10

MISSOURI STATE BOARD OF  
PHARMACY

  
Kimberly Grinston

Executive Director

Date

9-8-10

CHRIS KOSTER

Attorney General

  
Daryl Hylton

Assistant Attorney General

Missouri Bar No. 35605

Supreme Court Building

207 W. High St.

P.O. Box 899

Jefferson City, MO 65102

(573) 751-1444 Telephone

(573) 751-5660 Facsimile